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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/722,581	11/24/2003	Dan T. Simionescu	CXU-378	5668
22827	7590	01/23/2006	EXAMINER	
DORITY & MANNING, P.A. POST OFFICE BOX 1449 GREENVILLE, SC 29602-1449			PREBILIC, PAUL B	
			ART UNIT	PAPER NUMBER
			3738	
DATE MAILED: 01/23/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/722,581

Applicant(s)

SIMIONESCU ET AL.

Examiner

Paul B. Prebilic

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02 November 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,3-15 and 34-40 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-9 and 34-40 is/are rejected.
- 7) ☒ Claim(s) 10-15 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>11/2/05</u> . | 6) <input type="checkbox"/> Other: _____  |

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 34 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 34 appears to merely set forth a naturally occurring material or tissue of a living organism. Since Wiethoff (US 2005/0065430), in paragraph [0046] provides evidence that natural blood vessels are 30% dry weight elastin, the Examiner asserts that a natural valve leaflet, which is part of a natural blood vessel, would also have about 30% by weight elastin content. For this reason, the claim language appears to set forth a naturally occurring portion of a living organism.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 35 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 35 is considered indefinite because base claim 34 sets forth "a natural tissue." For this reason, the Examiner queries how a "fixed" tissue can still be considered "natural" since it has been modified by man. In other words, it is unclear when a natural material becomes artificial tissue if a tissue modified by man is

not considered "unnatural" or "artificial." As a result, the scope of "natural tissue" is considered to be indefinite.

### ***Claim Objections***

Claims 10-15 are objected to because of the following informalities:

With regard to claims 10-15, it is unclear whether the preamble is required in the body of the claim or not, and whether or how the support structure is associated with the remainder of the bioprosthetic heart valve; see claim 10. In order to overcome this objection, the Examiner suggests inserting the language ---to support the tissue of said bioprosthetic heart valve--- after "stent" on line 5 of claim 10. Appropriate correction is required.

### ***Election/Restrictions***

Claims 16-33 were withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on November 2, 2005. Non-elected claims 16-33 have been cancelled.

### ***Terminal Disclaimer***

The terminal disclaimer filed on November 2, 2005 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US Serial Number 10/722,142 has been reviewed and is accepted. The terminal disclaimer has been recorded.

***Claim Rejections Based Upon Prior Art***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3, 4, 7, 9, 34, 35, and 37 are rejected under 35 U.S.C. 102(e) as being anticipated by Nguyen-Thien-Nhon (US 6,001,126) as evidenced by Goodall (article entitled "The Association Between Venous Structural . . . ") or Wiethoff et al (US 2005/0065430), or, in the alternative, under 35 U.S.C. 103(a) as obvious over Nguyen-Thien-Nhon (US 6,001,126) alone. Nguyen-Thien-Nhon anticipates the claim language where the support material as claimed is the fabric (28) of Nguyen-Thien-Nhon and the elastin content is asserted to be inherently present in the tissues disclosed by Nguyen-Thien-Nhon; see the figures, the abstract, column 4, line 17 to column 5, line 33 and column 6, lines 7-52. Goodall (see page 940) and Wiethoff (see paragraph [0046]) both

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provide evidence that blood vessels, as used by Nguyen-Thien-Nhon, inherently contain 30% or more elastin content; see Goodall on page 940 where the elastin content of the intima tissue is 38.9% to 42.5% by weight and the other layers are about 30% elastin as claimed because they round up to that amount.

Alternatively, one may reasonably assert that the about 30% by weight elastin limitation is not met by Nguyen-Thien-Nhon. However, since the elastin content of 30% is not disclosed as critical (only 10% elastin seems to be critical), the Examiner asserts that it would have been prima facie obvious to use tissues that were 30% elastin so that the tissue used matches the elastin content found in healthy blood vessel tissue.

With regard to claim 8, the fabric (28) is considered to be a suture ring as claimed.

Claims 34-36 are rejected under 35 U.S.C. 102(e) as being anticipated by Yang (US 2003/0078659). Yang anticipates the claim language where the tissue of Yang, in at least one stage of making the device, can be called a valve leaflet of natural tissue and thus read on the claim language; see paragraphs [0025] and [0033] to [0035].

The Examiner asserts that porcine vena cava tissue as disclosed by Yang inherently has greater than 30% by weight elastin content due to its elastic nature. And due to its similarity to the claimed material, it reasonably appears to have the claimed weight percent of elastin.

Claims 1, 3-6, and 38-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yang (US 2005/0078659) in view of Kurland (US 4,400,833). Yang discloses a bioprosthetic of fixed vena cava tissue, but fails to clearly disclose a support

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structure therefor. However, Kurland teaches that it was known to use support layers for similar implants in order to improve the integrity and suturability of such tissues; see the abstract, Figures 1-4 and 19-22, and column 3, line 10 et seq. Therefore, it is the Examiner's position that it would have been prima facie obvious to use a support structure with a polymeric fabric with the Yang tissue for the same reasons that Kurland uses the same.

With regard to claims 3 and 4, since the stiffness and elasticity is not compared to any known value, it is considered inherently met by any material with some elasticity and stiffness. Furthermore, the Examiner asserts that the anisotropic property is inherent to the tissue because this limitation only requires that there be some non-uniformity in any characteristic. Since all materials have at least some slight non-uniformities, the claim language is considered inherently fully met.

Claims 1, 7, and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Gregory (US 5,990,379). Gregory anticipates the claim language where the material produced by Gregory is a modified natural tissue, and it inherently contains close to 100% elastin since all other materials have been removed; see the abstract and column 4, line 15 to column 5, line 18.

With regard to claim 8, the stent of Gregory is considered to be a suture ring to the extent that this language can be given patentable weight because the stent can be used to attach sutures to the elastin tissue.

***Allowable Subject Matter***

Claims 10-15 are objected to but would be allowable if rewritten to overcome the objection set forth *supra*.

***Response to Arguments***

Applicant's arguments filed November 2, 2005 have been fully considered but they are not persuasive.

In response to the traversal that the Gregory material is not natural tissue as claimed, the Examiner asserts that it is unclear when a natural tissue becomes unnatural based upon Applicants' specifications and claims. In particular, since Gregory discloses a tissue made of naturally occurring elastin, the Examiner asserts that it falls within the claim scope. This is due to the fact that "natural tissue" as used in the specification and claims apparently encompasses materials that have been modified by man; e.g. crosslinked or fixed tissue. For this reason, the rejection has been maintained.

With regard to the traversal of the Nguyen-Thien-Nhon rejection, the rejection has been modified in order to address the claims in their amended form. Applicants are directed to the new reasoning of the modified rejection as an answer to their arguments.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).



A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action if the application is not stored in image format (i.e. the IFW system) or published.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Paul B. Prebilic whose telephone number is (571) 272-4758. He can normally be reached on 6:30-5:00 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, McDermott Corrine can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
**Paul B. Prebilic**  
Primary Examiner